Remarks

Reconsideration is respectfully requested in light of the foregoing amendment and the remarks that follow.

After entry of the amendment, claims 36-37, 39-43, 45-52 and 54-59 are pending in this application.

Claims 36, 40, 42, 46, and 48 have been editorially amended and are supported by the specification at, for example, page 29, lines 10-11; page 31, lines 3-4. Claims 56-59 have been added and are supported by the specification at, for example, page 29, lines 10-11 and page 31, lines 3-4.

No issues of new matter should arise and entry of the amendment is respectfully requested..

First Rejection under § 103

Claims 36-40, 42-46, and 48-54 are rejected under 35 U.S.C. § 103(a) as obvious over Ukai et al. (U.S. Patent No. 6,576,677).

Applicant respectfully traverses the rejection.

Contrary to the PTO's assertions at page 4, line 7 to page 5, line 10 in the Office Action, the results in Ukai's Test 2 teaches away from the presently claimed formulation. Ukai teaches that the 2% percent polyvinylpyrrolidone solution in Test 2 performed poorly in reducing bitterness (i.e., 2.3 versus 4.3 on a scale of 1 to 5, with 1 being the most bitter; *see* Col. 5, Table 2), and the 2% percent polyvinylpyrrolidone solution performed worse than or the same as the control in reducing numbness in the three trials disclosed (i.e., 3.4 versus 3.9; 3.4 versus 3.4; 2.9 versus 3.4; *see* Col. 5, Table 2). The results in Ukai suggest to a one of skill in the art that such low amounts of polyvinylpyrrolidone are ineffective in reducing bitterness and numbness. Such a poor result cannot support the PTO's assertion that Ukai renders the claimed formulation obvious with respect to the claimed amounts of polyvinylpyrrolidone.

A. Claims 36-40, 42-46, and 48-54

Applicant respectfully submits that the obviousness rejection must be viewed in terms of the claim language and the teachings in Ukai. To this end, the independent claims recite polyvinylpyrrolidone having an average molecular weight from about 10,000 to about 100,000. Ukai teaches that polyvinylpyrrolidone can have an average molecular weight of 10,000 to

200,000. *See* Ukai et al. at column 2, lines 27-37. The upper limit of the average molecular weight of the claimed polyvinylpyrrolidone is 50% less than the upper limit of the average molecular weight of the polyvinylpyrrolidone described by Ukai.

At column 5, lines 1-7, Ukai teaches that the masking effects are heightened with increased amounts of polyvinylpyrrolidone. This is shown in Table 2. Optimization would require increased amounts of polyvinylpyrrolidone rather than the lower amounts required by the claims.

At column 2, lines 60-62, Ukai teaches that the "larger the molecular weight of polyvinylpyrrolidone, the less the amount of it to be added, while the smaller, the more the amount to be added." This sentence must be viewed in the context of Ukai teaching that the upper limit of the average molecular weight of polyvinylpyrrolidone can be 200,000 (i.e., 100% higher than the claimed upper limit of 100,000), and providing an example of a polyvinylpyrrolidone having an average molecular weight of 120,000 (i.e., 20% higher than the claimed upper limit of 100,000).

Ukai does not provide any relationship between the average molecular weight of polyvinylpyrrolidone and the amount used in the formulation. The difference between the claimed average molecular weight must be viewed in the context of the average molecular weights described by Ukai. The upper limit of the average molecular weight of 100,000 for the claimed polyvinylpyrrolidone is 50% and 17% less than the average molecular weight of 200,000 and 120,000 described by Ukai. Since the claimed invention is using a polyvinylpyrrolidone having a relatively low average molecular weight when compared to those described by Ukai, one skilled in the art would not expect to use an amount of polyvinylpyrrolidone as low as that claimed in the present invention.

Applicant respectfully requests that the rejection under 35 U.S.C. § 103 be withdrawn since a proper *prima facie* case has not been established.

B. Claims 40, 46, and 56-59

Applicant respectfully submits that claims 40, 46, and 56-59 are in condition for allowance based on the Examiner's analysis in the Office Action at page 3, lines 3-6. In each of these claims, the average molecular weight of polyvinylpyrrolidone is the same as or lower than the average molecular weight of polyvinylpyrrolidone described and exemplified in Ukai, i.e.,

polyvinylpyrrolidone having an average molecular weight of 40,000. *See* Ukai at column 2, lines 48-60; Examples 2-4, 7, 8.[1]

The Examiner's reasoning in the Office Action does not apply to claims where the formulation comprises polyvinylpyrrolidone having an average molecular weight the same as or lower than the average molecular weight of polyvinylpyrrolidone described and exemplified in Ukai (i.e., polyvinylpyrrolidone having an average molecular weight of 40,000). In fact, Ukai teaches away from the claimed amounts of polyvinylpyrrolidone for pending claims 40, 46, and 56-59, as shown in Ukai's specification at column 2, lines 60-62 (e.g., "...while the smaller, the more the amount to be added."). Applicant's claims are directed to exactly the opposite of what Ukai teaches. With respect to polyvinylpyrrolidones having a lower average molecular weight, Ukai teaches that a larger amount (i.e., > 2%) of such low molecular weight polyvinylpyrrolidone would be required in order to reduce the bitter taste and numbing qualities of the formulation to an acceptable level. In contrast, the present invention is based on the unexpected discovery that an acceptable reduction in bitterness and numbness may be achieved even when less (i.e., ≤ 2%) of such low molecular weight polyvinylpyrrolidone is employed. Applicant respectfully submits that a person of skill in the art of pharmaceutical formulations would consider Ukai to teach away from the present invention.

Applicant respectfully requests that the rejection under 35 U.S.C. § 103 be withdrawn since a proper *prima facie* case has not been established for claims 40, 46, and 56-59.

Second Rejection under § 103

Claims 41, 47, and 55 are rejected under 35 U.S.C. § 103(a) as obvious over Ukai et al. in view of Sugimoto et al., U.S. Patent No. 4,895,841.

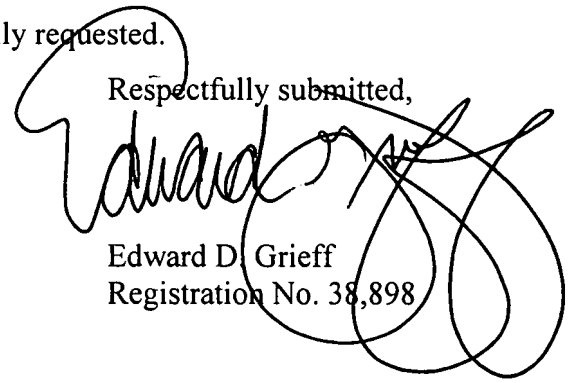
In view thereof, claims 36-40, 42-46, and 48-54 are unobvious over Ukai et al., claims 41, 47, and 55 would also be unobvious over Ukai et al. in view of Sugimoto, as Sugimoto does not cure the deficiencies of Ukai et al. In view thereof, Applicant respectfully requests that the rejection under 35 U.S.C. § 103 be withdrawn.

[1] Kollidon 30 used in Examples 3, 4, 7, 8 is the same polyvinylpyrrolidone having an average molecular weight of 40,000.

Conclusion

An early and favorable reconsideration and allowance of pending claims 36-37, 39-43, 45-52 and 54-59 is respectfully requested.

Respectfully submitted,



Edward D. Grieff
Registration No. 38,898

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Venable LLP
575 7th Street, NW
Washington, DC 20004
Phone: 202-344-4382